REMARKS

Claims 24-30 and 38-59 are pending in this application. Claims 24 and 38-40 are variously rejected under 35 U.S.C. §112, first paragraph. Claims 24 and 38-40 are variously rejected under 35 U.S.C. §102(e) or §103. Claims 24-30 and 38-59 are variously rejected under the judicially created doctrine of obviousness-type double patenting.

By this amendment, claim 24 has been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendment can be found, *inter alia*, throughout the specification and the claims as originally filed. For example, support for the amendment can be found at page 13, lines 15-27, of the substitute specification submitted May 10, 2005.

The amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants gratefully acknowledge the Examiner's indication in the Advisory Action that the response and affidavit submitted on October 11, 2005 overcomes the new matter rejections and objection to the specification.

Applicants have carefully considered the points raised in the final Office Action and Advisory Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Examiner Interview

Examiner Ponnaluria graciously granted a telephonic interview with the undersigned on December 20, 2005. Applicants appreciate the time and effort given to the interview by Examiner Ponnaluria. Briefly, the outstanding written description, enablement and art rejections were discussed. Applicants and Examiner agreed to consider possible amendments to claims and Applicants agreed to file an RCE.

Affidavit filed October 11, 2005

In the Advisory Action, the Examiner asked Applicants to clarify which pages of the specification were amended in the Preliminary Amendment filed August 18, 2003. As stated in the Affidavit, the Preliminary Amendment added new paragraphs "at pages 28 and 66 of the originally filed specification." These new paragraphs correspond to paragraphs in bold on pages 17-19 and 42-54 in the "Specification as Filed with Preliminary Amendment on August 18, 2003" submitted on May 10, 2005. These paragraphs are also found at pages 16-19 and 41-52 in the clean version of the substitute specification submitted on May 10, 2005. The Examiner is encouraged to contact Applicants' representative with any remaining questions on this matter.

Rejections under 35 U.S.C. §112, first paragraph

Claims 24 and 38-40 were rejected as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 24 and 38-40 were also rejected for allegedly not enabling any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Applicants respectfully traverse these rejections.

As amended herein, the claimed invention is directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administration of an amylin or an amylin agonist analogue to the mammal, wherein the amylin agonist analogue is a peptide. The specification both describes and enables peptidic amylin analogues agonists for use in the claimed invention.

To meet the written description requirement, the applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Ex parte Anderson*, 21 USPQ 2d, 1241, 1249 (BPAI, 1991). "Adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is

claimed." *Ex parte Parks*, 30 USPQ 2d, 1234 (BPAI, 1993)(citations omitted). In addition, courts have ruled that, to meet the written description requirement, an applicant is not required to re-describe that which is already known or readily determined by known procedures. (See *Capon v. Eshhar*, 418 F.3d 1349).

As noted at page 13 of the substitute specification, the term "amylin agonist analogues" refers to derivatives of an amylin which act as amylin agonists. The specification provides many examples of amylin analogue agonist peptides for use in the claimed invention. Specific examples of these peptidic agonist analogues are indicated in the specification by the name of the amylin peptide on which the analogue is based together with the type and location of the modification. See, for example, pages 19-20 of the substitute specification.

The specification provides physical and chemical characteristics, including receptor binding activity, of exemplary amylin agonist analogues, as well as, functional characteristics of exemplary amylin agonist analogues such as moderating the postprandial rise in plasma glucose, reducing gastric motility, slowing gastric emptying, and demonstrating amylin activity in a soleus muscle assay. See, for example, pages 30-40 and 42-52 of the substitute specification. Applicants respectfully submit that the specification in combination with that known in the art provides a description of sufficient, relevant, identifying structural and functional characteristics of an amylin agonist analogue peptide to adequately describe possession of the claimed genus to one skilled in the art. Thus, the pending claims are fully described in the specification as filed.

It is well established that "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971) (emphasis in original). Furthermore, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement made in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id., at 224 (emphasis in original).

Applicants respectfully submit that the specification has provided adequate direction and guidance to the skilled artisan with respect to making and using amylin agonist analogue peptides and that the skilled artisan would be able to extend the teachings of the specification and the art to the claimed methods without undue experimentation. For example, pages 23-25 and 42-49 of the substitute specification describe methods for making the disclosed and additional peptidic amylin agonist analogues. At pages 21-22, 30-40, and 49-52, the substitute specification provides methods by which the skilled artisan can assess the activity of any amylin agonist analogue peptide, for example, in receptor binding assays, soleus muscle assays, gastric motility assays, and postprandial plasma glucose assays. At page 13, the substitute specification describes that amylin agonist analogues peptides were known in the art at the time the application was filed. Further it is respectfully submitted that the Patent Office has not produced evidence or reasoning to doubt the truth of the enabling statements of the disclosure. Thus, Applicants respectfully submit that a *prima facie* case of lack of enablement has not been established and the pending claims are in compliance with the enablement requirements.

In sum, Applicants submit that the pending claims fall within the subject matter that is described and enabled by the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

Rejections under 35 U.S.C. §§102/103

Claims 24 and 38 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Liu et al. (U.S. Pat. No. 6,136,820; "Liu"). Claims 24 and 38-40 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Liu or alternatively rejected under 35 U.S.C. §103 as allegedly obvious over Liu in view of Meezan et al. (U.S. Pat. No. 5,817,634; "Meezan"). Applicants respectfully traverse these rejections.

As amended, claim 24 is directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administration of an amylin or an amylin agonist analogue to the mammal, wherein the amylin agonist analogue is a peptide. Claim 38 is directed to the method of claim 24 wherein the mammal has diabetes.

Liu describes treating diabetes and postprandial hyperglycemia in diabetic individuals through administration of castanospermine, an alkaloid. Castanospermine is not an amylin or an amylin agonist analogue peptide. Liu does not teach administration of an amylin or an amylin agonist analogue peptide. Liu does not teach administration of an amylin or an amylin agonist analogue for reducing or moderating a postprandial rise in plasma glucose in a mammal. Since Liu does not teach each and every element of the claim, the reference does not anticipate the claimed invention.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The background section of Meezan discusses that diabetes mellitus is characterized by hyperglycemia and presents as two major subtypes, Type I and Type II. The combination of Liu and Meezan provides no teaching or suggestion of the use of an amylin or an amylin agonist analogue for reducing or moderating a postprandial rise in plasma glucose. Thus, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

In sum, Applicants respectfully submit that the cited references neither anticipate nor make obvious the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §§102(e)/103.

Rejections under Obviousness-type Double Patenting

Claims 24-30 and 38-59 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-35 of U.S. Pat. No. 6,114,304. Claims 24-30, 38, 40-57, and 59 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-18 of U.S. Pat. No. 6,417,164. Although Applicants disagree with these rejections, in order to facilitate prosecution, Applicants are willing to consider submitting a terminal disclaimer in the present application with regard to the cited patents upon indication of allowable subject matter.

CONCLUSION

Applicants believe that all issues raised in the final Office Action and Advisory Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No further fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 18528.642. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535 referencing Docket No. 18528.642.

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Respectfully submitted,

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